

The following is submitted in response to the office action of September 21, 2004.

REMARKS

Reconsideration is respectfully requested in view of the remarks which follow.

Claims 38-59 stand rejected under 35 USC 112, first paragraph, since it is the Examiner's opinion that the specification does not reasonably provide enablement for any buffer of any mg range. This rejection is respectfully traversed.

In the claimed invention applicant has unexpectedly found that-- completely contrary to the teachings of the prior art -- *a preservative is not needed* to maintain the stability of the derivatives and analogues of oxytocin and vasopressin for at least eighteen months at room temperature, provided the pH of the composition is maintained between 3.5 and 6 through the use of a buffer in aqueous solution.

The prior art, as exemplified by Harris, *teaches the necessity of a preservative* to maintain the stability of small peptides in solution, and to prevent their adsorption onto the walls of the container. Applicant has, by contrast, found that *a preservative is not needed* and that the stability of the composition can be maintained for eighteen months absent any preservative. Eighteen month stability and the absence of adsorption onto the container walls are achieved by applicant by employing a buffer system which provides the composition with a pH between 3.5 and 6.0.

Applicant next addresses the Examiner's statement that the disclosure "does not reasonably provide enablement for any buffer of any mg range." It is respectfully submitted that the buffer systems set forth in applicant's examples provide a reduction to practice of buffers having a pH between 3.5 and 6.0 which are effective in preventing adsorption, and

which would provide one of ordinary skill in the art with the requisite guidance, direction and information to avoid the need for *undue experimentation* in order to identify and select other effective buffers that would perform in a similar manner.

Since the maintenance of stability and adsorption prevention are based on providing a rather straightforward buffer system within a circumscribed pH range, a chemist of ordinary skill in the art would have no difficulty in the preparation of similar systems without the need to engage in *undue experimentation*.

As the CCPA held in In re Bowen, 181 USPQ 48 (1974), the Patent Office holding that an application does not comply with the enablement portion of §112, must provide reasons why it considers that it is uncertain that a class of materials will work in a claimed process in contravention to the application's statement that the invention, in its broader aspects, is applicable to materials other than those disclosed as operative in the claimed process. *In Bowen*, Judge Rich speaking for a unanimous court reversed the Board of Appeals which had upheld the Examiner and stated that there appeared to be no basis for the non-enablement rejection on the theory that the claims read on undisclosed polymers. In this case, the only disclosed polymer was a polyamide, i.e., polyhexamethylene adipamide, which the Examiner maintained was non-enabling to support recitation in the claim of a "melt-polymerizable material". Judge Rich stated, "[W]hile the claims literally comprehend numerous polymers in addition to the ones specifically described in appellant's specification, nylon 66, no persuasive reason has been given by the Patent Office why the specification does not realistically enable one skilled in the art to practice the invention as broadly as it is claimed."

In a 1987 decision, the Federal Circuit in a similar vein said in Gould v. Quigg,

3 USPQ 2d 1302 that “there is no requirement in 35 USC §112 or anywhere else in the patent law that a specification convince persons skilled in the art that the assertions in the specification are correct...”. In examining a patent application, the PTO is required to assume that a specification complies with the enablement provision of §112, unless it has acceptable ‘evidence or reasoning’ to suggest otherwise.

It is respectfully submitted that in light of the *Bowen* and *Gould* decisions, the two buffer systems disclosed in the examples of the instant application would teach one of ordinary skill in the art how to successfully maintain stability for eighteen months and how to prevent adsorption onto the container walls, and there is no basis in law or in fact to doubt that other such systems would work equally well in the absence of a preservative. There is no requirement in the law that every such buffer system be detailed in *blueprint-like fashion* in order for a buffer system operating at pH 3.5-6 to be enabled in the sense of §112, paragraph 1.

The Federal Circuit also held in Atlas Powder Co. v. E.I. DuPont De Nemours & Co., 224 USPQ 409, 414 with respect to the issue of the claims reading on the issue of possible inoperative embodiments that, “[I]t is not a function of claims to specifically exclude *** possible inoperative substances ***” In re Dinh-Nguyen, 181 USPQ 46, 48 (CCPA 1974).

With regard to the question of undue experimentation, the CAFC held in Enzo Biochem, Inc v. Calgene, Inc. 52 USPQ 2d 1129 (1999) that a patent specification complies with the statute even if a “reasonable amount” of routine experimentation is required in order to practice a claimed invention, but that such experimentation must not be “undue”: See, e.g., In re Wands, 8 USPQ 2d 1404 “Enablement is not precluded by the necessity of some

experimentation..."). However, the experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue', not 'experimentation'. In *In re Wands*, the Court set forth a number of factors which a court may consider in determining whether a disclosure would require undue experimentation. These factors are:

1. 'the quantity of experimentation necessary';
2. 'the amount of direction or guidance presented';
3. 'the presence or absence or working examples';
4. 'the nature of the invention';
5. 'the state of the prior art';
6. 'the relative skill of those in the art';
7. 'the predictability or unpredictability of the art; and
8. 'the breadth of the claims'.

Applying the Wands factors to the facts herein, the determination of buffer systems operating at pH 3.5 - 6 which would serve to stabilize small to medium size peptides based upon the examples provided in the specification would certainly be deemed to be adequate and sufficient to instruct one of ordinary skill in the art without "undue experimentation" especially in view of the relatively straightforward nature of the invention.

The Federal Circuit in *Ajinomoto Co, Inc. v Archer-Daniels Midland Co.* 56 USPQ 2d 1332 (2000) stated that "the Federal Circuit, in its enablement decisions, has emphasized that the patent's claims need not specifically exclude possible inoperative substances in order to be enabled, unless the number of inoperative combinations becomes significant and in fact forces one of ordinary skill in the art to *experiment unduly* in order to practice the claimed

invention."

Similarly, the Board of Patent Appeals and Interferences in 1988 held in Horton v Stevens at 7 USPQ 2d 1245, 1247, that "the mere fact that a claim embraces undisclosed or inoperative species or embodiments does not necessarily render it unduly broad."

Also, in a 1983 case the PTO Board of Appeals held in Ex Parte Cole et al. at 223 USPQ 94, 95-96 that, "claims are addressed to the person of average skill in the particular art. Compliance with §112 must be adjudged from that perspective, not in a vacuum. It is always possible to theorize some combination of circumstances which would render a claimed composition or method inoperative, but the art-skilled would assuredly not choose such a combination."

Certainly, when the facts herein are viewed through the lens of the applicable case law as set forth above, a compelling mandate is provided for the withdrawal of the §112, paragraph 1, rejection for non-enablement since, quite clearly, a *prima facie* case of non-enablement has not been established.

Accordingly, it is respectfully requested that the §112 rejection be withdrawn and the application be allowed.

The issuance of a Notice of Allowance is respectfully solicited.

Please charge any fees which may be due and which have not been submitted herewith
to our Deposit Account No. 01-0035.

Respectfully submitted,

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